IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF WYOMING

GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED Plaintiff, v. FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC, d/b/a/ FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA SALES, INC., FRESENIUS MEDICAL CARE AG & CO. KGaA Defendants.	)	Civil Action No. 16CV180-F

COMPLAINT AND DEMAND FOR TRIAL BY JURY

COMES NOW the Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED ("Plaintiff") by and through his attorney, Jason Edward Ochs, Ochs Law Firm, P.C., and for his Complaint against the Defendants, FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS MEDICAL CARE HOLDINGS d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS

USA MANUFACTURING, INC., FRESENIUS USA SALES, INC., FRESENIUS MEDICAL CARE AG & CO. KGaA ("Defendants") and hereby state and allege as follows:

I. NATURE OF CASE

1. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, brings this survival action to recover for personal injuries and economic damages suffered as a direct and proximate result of the negligent and wrongful conduct of Defendants in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of a home peritoneal dialysis machine, sold as the Fresenius Liberty Cycler system ("Liberty Cycler system") manufactured by designed, developed, manufactured, reprocessed, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants.

II. PARTIES

2. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, is a resident of Kemmerer, Lincoln County, Wyoming. He is the biological father to JENELL S. PUTNAM and has been appointed the personal representative of JENELL S. PUTNAM'S estate on May 16, 2016 in Albany County; a true and correct copy of said Order is attached hereto as *Exhibit A*.

3. Decedent, JENELL S. PUTNAM, died on the 21st day of February, 2015, in Albany County, State of Wyoming and was a resident of Albany County, Wyoming at the time of her death.

4. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

5. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing promoting, selling and distributing dialysis products including but not limited to the Liberty Cycler home dialysis machine and related parts.

6. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has transacted and conducted business throughout the United States, including but limited to the State of Wyoming.

7. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has derived substantial revenue from goods and products designed, manufacture red, marketed, advertised, prompted, sold and/or distributed throughout the United States, including but limited to the State of Wyoming.

8. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. derives substantial revenue from interstate commerce throughout the United States, including but not limited to the State of Wyoming.

9. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a/ FRESENIUS MEDICAL CARE NORTH AMERICA is a for profit corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

10. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a/

FRESENIUS MEDICAL CARE NORTH AMERICA, according to its website, it is the world's largest integrated provider of products and services for renal care products. It provides products for chronic kidney disease and it manufactures and distributes a variety of dialysis products and equipment, including but not limited to dialyzers, dialysis-related supplies, and dialysis machines, including but not limited to the Liberty Cycler home dialysis machine.

11. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a/ FRESENIUS MEDICAL CARE NORTH AMERICA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing promoting, selling and distributing dialysis products including but not limited to the Liberty Cycler home dialysis machine and related parts.

12. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a/ FRESENIUS MEDICAL CARE NORTH AMERICA has transacted and conducted business throughout the United States, including but not limited to the State of Wyoming.

13. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a/ FRESENIUS MEDICAL CARE NORTH AMERICA has derived substantial revenue from goods and products designed, manufacture red, marketed, advertised, prompted, sold and/or distributed throughout the United States, including but not limited to the State of Wyoming.

14. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a/ FRESENIUS MEDICAL CARE NORTH AMERICA derives substantial revenue from interstate commerce throughout the United States, including but not limited to the State of Wyoming.

15. Defendant FRESENIUS USA MANUFACTURING, INC. is a corporation

organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

16. Defendant FRESENIUS USA MANUFACTURING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing promoting, selling and distributing dialysis products including but not limited to the Liberty Cycler home dialysis machine and related parts.

17. Defendant FRESENIUS USA MANUFACTURING, INC. has transacted and conducted business throughout the United States, including but not limited to the State of Wyoming.

18. Defendant FRESENIUS USA MANUFACTURING, INC. has derived substantial revenue from goods and products designed, manufacture red, marketed, advertised, prompted, sold and/or distributed throughout the United States, including but not limited to the State of Wyoming.

19. Defendant FRESENIUS USA MANUFACTURING, INC. derives substantial revenue from interstate commerce throughout the United States, including but not limited to the State of Wyoming.

20. Defendant FRESENIUS USA SALES, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

21. Defendant FRESENIUS USA SALES, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing promoting, selling

and distributing dialysis products including but not limited to the Liberty Cycler home dialysis machine and related parts.

22. Defendant FRESENIUS USA SALES, INC. has transacted and conducted business throughout the United States, including but not limited to the State of Wyoming.

23. Defendant FRESENIUS USA SALES, INC. has derived substantial revenue from goods and products designed, manufacture red, marketed, advertised, prompted, sold and/or distributed throughout the United States, including but not limited to the State of Wyoming.

24. Defendant FRESENIUS USA SALES, INC. derives substantial revenue from interstate commerce throughout the United States, including but not limited to the State of Wyoming.

25. Upon information and belief, Defendants, FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., and FRESENIUS USA SALES, INC. are wholly owned subsidiaries of Defendants FRESENIUS MEDICAL CARE HOLDINGS INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

26. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at Else-Kroner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

27. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, a partnership limited by shares was formerly known as FRESENIUS MEDICAL CARE AG, a stock

corporation. FRESENIUS MEDICAL CARE AG & CO. KGaA is the name legal business entity as FRESENIUS MEDICAL CARE AG.

28. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA is and was at all relevant times the parent company of defendants FRESENIUS MEDICAL CARE HOLDINGS, INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

29. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing promoting, selling and distributing dialysis products including but not limited to the Liberty Cycler home dialysis machine and related parts throughout the United States, including but not limited to the State of Wyoming.

30. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA has transacted and conducted business throughout the United States, including but limited to the State of Wyoming.

31. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, prompted, sold and/or distributed throughout the United States, including but limited to the State of Wyoming.

32. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA expected or should have expected to have its acts to consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

33. At all times herein alleged, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and joint venture of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty owed to Plaintiff.

34. There exists, and at all times herein alleged, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

III. JURISDICTION AND VENUE

35. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 and Wyo. Stat. § 1-4-101. There is complete diversity of citizenship between the parties and the amount in controversy as to the Defendants exceeds seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

36. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as this is the judicial district where a substantial number of the events, actions or

omissions giving rise to Plaintiff's claims occurred. At all times material hereto, Defendants were for profit corporations conducting substantial business in this district.

37. At all times material hereto, Defendants developed, designed, manufactured, reprocessed, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities involved in the sale and distribution of the Liberty Cycler system at issue in this matter. By said activities, Defendants' Liberty Cycler system are placed into the stream of commerce throughout the United States, including Albany County, State of Wyoming.

38. Defendants are subject to the personal jurisdiction of this Court as each systematically and continually conducts business in Albany County, Wyoming, and throughout the United States.

IV. GENERAL ALLEGATIONS

39. Plaintiff incorporates by reference all of the allegations contained in all preceding paragraphs as if fully set forth herein.

40. That Plaintiff/Decedent, JENELL S. PUTNAM, had been dialysis dependent since approximately age 18 due to a diagnosis of glomerulonephritis for which she received a kidney transplant.

41. In the 22 years of which Plaintiff/Decedent, JENELL S. PUTNAM had been dialysis dependent, she was able to complete the dialysis treatments at home, therefore giving her the ability to sustain a job and independently perform activities of daily living.

42. This claim seeks compensatory and punitive damages on behalf of Plaintiff, who used a home peritoneal Liberty Cycler dialysis machine designed, manufactured, marketed,

distributed and sold by Defendants. The peritoneal dialysis machine was known as the Fresenius Liberty Cycler system.

43. Defendants are collectively a major provider of kidney dialysis services and products that holds itself out as the world's largest integrated provider of products and services for individuals undergoing dialysis.

44. Defendant Fresenius is a publicly traded company that generated revenue of approximately $11.2 Billion in 2009 and revenue of more than $12 Billion dollars in 2010.

45. Defendants intensively and aggressively marketed and promoted the use of the Fresenius Liberty Cycler system by nephrologists, including the Plaintiff's nephrologists. Defendants also instructed physicians regarding the advantages of the Liberty Cycler system, and regarding their method of use of the Liberty Cycler system by patients.

46. The Liberty Cycler system has cycler sets for use in the peritoneal dialysis machines that are disposable.

47. A new cycler set is required each time a patient uses the Liberty Cycler system to undergo peritoneal dialysis.

48. The contents of the cycler set used in a Liberty Cycler system include tubing and a cassette.

49. Defendants developed, designed, manufactured, reprocessed, labeled, packaged, distributed, marketed, supplied, advertised, and sold the Liberty Cycler system including the cassettes to dialysis clinics and patients nationwide, including to patients within the State of Wyoming and to Plaintiff.

50. Peritonitis is an inflammation of the peritoneum, the tissue that lines the inner wall of the abdomen and covers and supports most of the abdominal organs.

51. Peritonitis is an infection usually caused by bacteria that rapidly spreads into the blood and organs and can result in multiple organ failure and death.

52. Peritonitis is a life threatening condition.

53. On or about April 2013, Plaintiff, JENELL S. PUTNAM's contracted peritonitis as the direct and proximate use of the unreasonably dangerous and defective Liberty Cycler System, she used for her home peritoneal dialysis which caused Plaintiff to suffer severe and permanent injuries and damages as alleged herein.

54. At all relevant times herein, prior to Plaintiff contracting peritonitis from the use of the Liberty Cycler system, Defendants knew or should have known of the unreasonably dangerous or defective condition of the Fresenius Liberty Cycler system. Although it knew or should have known about the defects in the Fresenius Cycler system at the time the Fresenius Cycler system was sold to Plaintiff, Defendants did not disclose that information to Plaintiff or her healthcare providers.

55. Despite a legal duty to disclose the information to Plaintiff and Plaintiff's healthcare providers, Defendants actively concealed problems with the Fresenius Cycler system.

56. On September 15, 2010, the United States Food and Drug Administration "("FDA") wrote a warning letter to Mr. Rice Powell, Chief Executive Officer of Fresenius Medical Care Holdings, Inc., notifying the Defendants of findings with respect to the Liberty Cycler system that caused injuries to the Plaintiff. The findings in pertinent part include:

a. Inspection revealed the devices, including Liberty Cycler sets of the Liberty Cycler system are "adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820."

b. Defendants investigated 118 complaints from January 2001 through October 2009 of cassette leaks during patient hemodialysis treatments which included two confirmed cases of peritonitis. Defendants identified a root cause, initiated shipping holds on existing inventory and ordered a product rework in November, 2009, but failed to identify an action to address units in commercial distribution at that time and those to be distributed at a future time.

c. During their own documented health hazard assessment, conducted according to Defendants own procedures, Defendants determined the "level of concern" (hazard) to be critical (i.e. death or serious injury) and the "likelihood of occurrence" to be remote which produced a risk acceptability result of "undesirable". And yet no actions were taken to identify or reduce the risks of products in the field and to permanently correct the design defect.

d. With respect to the Liberty Cycler cassettes in the Liberty Cycler systems, Defendants failed to establish and maintain an adequate corrective and preventive action procedure which ensured identification of actions needed to correct and prevent the recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3).

e. With respect to the Liberty Cycler cassettes in the Liberty Cycler systems, Defendants failed to establish and maintain procedures for verifying or validating corrective and preventive actions, to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). Defendants failed to take action despite receiving 42 additional complaints, which included 2 MDRs with confirmed cases of peritonitis related to identified lots in commercial distribution.

57. On or after October 22, 2013, Plaintiff received a letter from Defendants, entitled "***URGENT Safety Alert*** Liberty Cyclers; REASON: Liberty Cycler – Fluid Leaks," stating in pertinent part, "Fresenius Medical Care North America is initiating a voluntary safety alert involving Liberty Cyclers due to complaints that are typically described as a fluid leak. Fluid leaking may be observed inside the pump compartment of the Liberty Cycler with or without an obvious leak source (such as a leaky tubing connection, splash over priming the patient line or a hole in the liberty cassette film). This safety alert is intended to remind you of the safety procedures to follow in the event of Liberty Cycler fluid leaks…The cause

of the problem is currently being investigated. In the unlikely event that there is a fluid leak inside the cycler, there is a remote possibility that dialysate may become contaminated, and potentially result in an infection called peritonitis."

58. Prior to, on, and after the dates of Plaintiff's use of the Liberty Cycler system, Defendants knew that Liberty Cycler system was defective and harmful to consumers and that the Liberty Cycler system had an unacceptable risk of contamination. Defendants had a legal and moral obligation to stop selling the product and to notify physicians and or patients who had purchased and or used the Liberty Cycler system to be aware of the propensity for the Liberty Cycler system to have a fluid leak that could lead to contamination of the dialysate and result in peritonitis in the patient.

59. The Defendants misled the public at large, including Plaintiff and Plaintiff's healthcare providers, by making false representations about the safety of the Liberty Cycler system; they downplayed, understated and/or disregarded their knowledge of the defects, contamination, and side effects associated with the Liberty Cycler system, despite available information to the contrary.

60. The Defendants, by and through an officer, director, or managing agent, authorized sales representatives, employees and/or other agents to engage in malicious, fraudulent, and oppressive conduct towards the public, including Plaintiff, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of the general public and of Plaintiff.

61. The acts and/or omissions of Defendant as set forth supra, were also such knowing and willful failures to warn of adverse effects inherent in the use of the Liberty Cycler system, that they constituted malicious, willful, wanton, and/or reckless conduct.

62. Plaintiff is entitled to punitive damages because failure of the Defendants to communicate warning information, or adequate warning information, and their affirmative dissemination and adoption of dangerous misinformation and disinformation, was reckless and without regard for the public's safety and welfare.

COUNT I

STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

63. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein.

64. Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling directly and indirectly through third parties or related entities the Fresenius Liberty Cycler system.

65. Defendants had a duty to place into the stream of commerce, manufacture, distribute, design, test, promote and sell the Fresenius Liberty Cycler system so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

66. The Fresenius Liberty Cycler system that the Plaintiff used was defective and unreasonably dangerous.

67. At all times material to this action, the Fresenius Liberty Cycler system was expected to reach, and did reach, consumers and healthcare providers in the States of Wyoming and throughout the United States, including decedent Jenell Putnam, without substantial change in the condition in which it was sold. At the time the Fresenius Liberty Cycler system left the possession of defendants, and the time the Fresenius Liberty Cycler system entered the stream of commerce, the Fresenius Liberty Cycler system was in an unreasonably dangerous and defective condition. These defects include, but are not limited to defects in the design, development, manufacturing, testing, and or packaging that causes a fluid leak within the Liberty Cycler. The fluid leak causes dialysate to become contaminated and can cause peritonitis infection in the user of the Liberty Cycler system.

68. Plaintiff could not have discovered any defect in the Fresenius Liberty Cycler system through reasonable care.

69. Defendants as designer, manufacturer, marketer, and distributor of the Fresenius Liberty Cycler system, are held to the level of knowledge of an expert in its field.

70. Neither Plaintiff/Decedent nor Plaintiff's/Decedent's healthcare providers had substantially the same knowledge as the Defendants.

71. Plaintiff/Decedent, nor her healthcare providers were able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Fresenius Liberty Cycler system.

72. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the Fresenius Liberty Cycler system and

the Defendants' failure to comply with federal standards and requirements, the Plaintiff/Decedent suffered severe and permanent injuries. Plaintiff/Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered severe pecuniary loss. Plaintiff/Decedent seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

73. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff/Decedent herein, thereby entitling Plaintiff/Decedent to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT TWO

STRICT PRODUCTS LIABILITY - FAILURE TO WARN DEFECT

74. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein.

75. Defendants were the manufacturer, designer, reprocessor, distributor, seller, and/or supplier of the Fresenius Liberty Cycler system.

76. The Fresenius Liberty Cycler system was defective and unreasonably dangerous when it left the possession of the respective Defendants in that it contained warnings insufficient

to alert consumers, including Plaintiff/Decedent, and healthcare providers, including Plaintiff's / Decedent's healthcare providers, of the dangerous risks associated with the Fresenius Liberty Cycler system, including but not limited to its propensity to cause a substantial increased risk of serious bodily harm and death, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects.

77. The Fresenius Liberty Cycler system was used by Plaintiff/Decedent, and Plaintiff/Decedent used the Fresenius Liberty Cycler system for its intended purpose.

78. Plaintiff/Decedent could not have discovered any defect in the Fresenius Liberty Cycler system through the exercise of reasonable care.

79. Defendants as designer, manufacturer, marketer, and/or distributor of the Fresenius Liberty Cycler system, are held to the level of knowledge of an expert in its field.

80. The warnings that were given by the Defendants were not timely, accurate, clear, and/or were ambiguous.

81. The warnings that were given by the Defendants failed to properly warn physicians or consumers of the risk of the Fresenius Liberty Cycler system for patients.

82. Plaintiff/Decedent, individually and through Plaintiff's prescribing/treating physician, reasonably relied on the skill, superior knowledge, and judgment of the Defendants.

83. Had Plaintiff/Decedent received adequate warnings regarding the risks of the subject product, Plaintiff/Decedent would not have used it.s a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of the Fresenius Liberty Cycler system and the Defendants' failure to comply with federal standards and requirements, Plaintiff/Decedent suffered severe and permanent injuries, including. Plaintiff/Decedent endured substantial conscious pain and suffering, both

physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered severe pecuniary loss. Plaintiff/Decedent seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

84. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff/Decedent herein, thereby entitling Plaintiff/Decedent to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT III

STRICT PRODUCTS LIABILITY - DESIGN DEFECT

85. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein.

86. Defendant was the manufacturer, designer, re-processor, distributor, and sold into the stream of commerce the Fresenius Liberty Cycler system.

87. The Fresenius Liberty Cycler system that was used by the Plaintiff/Decedent was defective in its design when it left the hands of Defendants, in that the design was flawed thereby posing a serious risk that the dialysate could become contaminated and cause peritonitis in patients. Peritonitis causes injuries including but not limited to physical injury, pain, suffering, debilitation, and complications.

88. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of the Fresenius Liberty Cycler system and the Defendants' failure to comply with federal standards and requirements, Plaintiff/Decedent suffered severe and permanent injuries, including but not limited to physical injury, pain, suffering and debilitation.

89. Plaintiff/Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered pecuniary loss. Plaintiff/Decedent seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein were catastrophic, irreversible and permanent.

90. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff/Decedent herein, thereby entitling Plaintiff/Decedent to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT FOUR

NEGLIGENCE

91. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein.

92. At all times material hereto, the Defendants, and each of them individually, had a duty to exercise reasonable care to consumers, including Plaintiff/Decedent herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of the Liberty Cycler system.

93. The Defendants, and each of them individually, breached their duty of reasonable care to Plaintiff/Decedent in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold the Liberty Cycler System.

94. Plaintiff's/Decedent's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of the Defendants.

95. Defendants' negligence in designing, testing, manufacturing, distributing, marketing, promoting, and selling the Liberty Cycler system includes, but is not limited to, the following:

a. In their design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of the Liberty Cycler system.
b. The cassette inside the Cycler set was negligently designed and manufactured creating increased likelihood of leakage and contamination of the dialysate resulting in infection.
c. Failing to recall, retrofit, or warn patients or physicians about the dangers of the Liberty Cycler system prior to, and on the date of Plaintiff's injury.

96. Defendants knew or had reason to know that Plaintiff, as a member of the general public for whose use the Liberty Cycler System was placed into interstate commerce, would be likely to use the Liberty Cycler System in a manner described in this Complaint.

97. Defendants knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the Liberty Cycler System, which danger would not be obvious to the general public.

98. The Defendants knew or should have known that consumers such as Plaintiff/Decedent herein would foreseeably suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.

99. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the Liberty Cycler System and the Defendants' failure to comply with federal standards and requirements, the Plaintiff/Decedent suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff suffered pecuniary loss. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein were catastrophic, irreversible and permanent.

COUNT FIVE

BREACH OF EXPRESS WARRANTY

100. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein.

101. Defendants expressly warranted that the Liberty Cycler System was safe and fit for use by consumers and users, including Plaintiff, for its intended use, that it was of

merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

102. At the time of the making of the express warranties, the Defendants knew or should have known of the purpose for which the Liberty Cycler System was to be used and warranted the same to be, in all respects, fit, safe, effective, and proper for such purpose. At the time Defendants marketed, sold and/or distributed the Liberty Cycler System, Plaintiff was a foreseeable user of the device.

103. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the Liberty Cycler System were not safe and fit for their intended use and, in fact, produced serious injuries to consumers using the product.

104. Members of the medical community including, but not limited to, Plaintiff's healthcare providers, reasonably relied upon the skill and judgment of Defendants, and upon said express warranties in selecting the Liberty Cycler System for Plaintiff.

105. Plaintiff and Plaintiff's healthcare providers relied on the Defendants' express warranties. Plaintiff used the Liberty Cycler System and did use it for its intended purpose.

106. Defendants breached said express warranties, in that the Liberty Cycler System were not safe and fit for its intended use and, in fact, caused debilitating and potentially lethal side effects to patients when used for its intended purposes.

107. At the time Defendants marketed, sold and/or distributed the Liberty Cycler System, it expressly warranted that the device, including all of its component parts, was safe and merchantable for its/their intended use.

108. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the representations that the Liberty Cycler System was of merchantable quality and safe for its intended use.

109. Plaintiff used the Liberty Cycler System for its intended use.

110. Contrary to the expressed warranties, at the time Defendants marketed, sold and/or distributed the Liberty Cycler System, it was not of merchantable quality or safe for its intended use as described above.

111. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the Liberty Cycler System and the Defendants' failure to comply with federal standards and requirements, the Plaintiff/Decedent suffered severe and permanent injuries. Plaintiff/Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered pecuniary loss. Plaintiff/Decedent seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein were permanent.

COUNT SIX

BREACH OF IMPLIED WARRANTY

112. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein paragraphs and further alleges as follows:

113. The Defendants designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold the Liberty Cycler System.

114. At the time that the Defendants designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold the Liberty Cycler System they knew of the use for which it was intended and impliedly warranted the Liberty Cycler System to be of merchantable quality and safe and fit for such use.

115. Plaintiff, individually and through Plaintiff's healthcare providers, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants.

116. Plaintiff used Liberty Cycler System for its intended purpose.

117. Due to the Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the Liberty Cycler System until after Plaintiff used it.

118. Contrary to the implied warranties for the Liberty Cycler System, the product was not of merchantable quality and was not safe or fit for its intended use and purpose, as alleged herein.

119. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the Liberty Cycler System and the Defendants' failure to comply with federal standards and requirements, the Plaintiff suffered severe and permanent injuries. Plaintiff/Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered severe pecuniary loss. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein were permanent.

120. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff/Decedent herein, thereby entitling Plaintiff/Decedent to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT SEVEN

NEGLIGENT MISREPRESENTATION

121. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein paragraphs and further alleges as follows:

122. The Defendants labeled, promoted, and advertised the Liberty Cycler System as safe, fit and effective for use in humans.

123. The Defendants are the manufacturers, designers, distributors, sellers or suppliers of the Liberty Cycler System and, while engaged in the course of such business, made representations to Plaintiff and Plaintiff's healthcare providers regarding the character and/or quality of the Liberty Cycler System for guidance in their decision to select the Liberty Cycler System for Plaintiff's use.

124. Defendants knew or should have known that the Liberty Cycler System could leak and contaminate dialysate infusing directly into Plaintiff thereby giving rise to peritonitis, subjecting patients to unnecessary pain and suffering, debilitation, and complications. The fact that the Liberty Cycler System was known to Defendants to leak and cause contamination is a material fact.

125. Defendants recklessly and/or negligently made false representations of material fact to Plaintiff, and Plaintiff's healthcare providers, including but not limited to claims that the Liberty Cycler System was a safe and effective home peritoneal dialysis system.

126. Defendants' representations regarding the character and/or quality of the Liberty Cycler System were untrue.

127. At the time Defendants concealed the fact that the Liberty Cycler System was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with the Liberty Cycler System.

128. Plaintiff's healthcare providers relied upon Defendants misrepresentations regarding the safety of the Liberty Cycler System and would not have exposed Plaintiff to the Liberty Cycler System had Plaintiff's healthcare providers known or otherwise been aware of the true facts concerning the Liberty Cycler System.

129. Plaintiff and Plaintiff's healthcare providers reasonably relied, to their detriment, upon the Defendants' actions, concealment and omissions in their representations concerning the effectiveness, safe, and risks of the Liberty Cycler System.

130. In reliance on Defendants' misrepresentations of material fact, Plaintiff and Plaintiff's healthcare providers decided to use and did use the Liberty Cycler System for Plaintiff. Had Plaintiff known the true facts regarding the Liberty Cycler System, Plaintiff would not have consented to using the Liberty Cycler System. Had Plaintiff's healthcare providers known the true facts regarding the Liberty Cycler System, they would not have used the Liberty Cycler System for Plaintiff.

131. Defendants' conduct tolled the statute of limitations because only Defendants knew or should have known the true dangers associated with the Liberty Cycler System as

described herein. Defendants did not disclose this information to the Plaintiff, her healthcare providers, the healthcare community and the general public. The dangers associated with the Liberty Cycler System were not known to the general public until after Plaintiff contracted peritonitis from her Liberty Cycler System. Without full knowledge of the dangers of the Liberty Cycler System Plaintiff could not, through reasonable diligence, discover that Plaintiff had a valid claim.

132. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the Liberty Cycler System and the Defendants' failure to comply with federal standards and requirements, the Plaintiff/Decedent suffered severe and permanent injuries. Plaintiff/Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered pecuniary loss. Plaintiff/Decedent seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein were permanent.

COUNT EIGHT

INTENTIONAL MISREPRESENTATION AND FRAUDULENT CONCEALMENT

133. Plaintiff, GEORGE PUTNAM, PERSONAL REPRESENTATIVE OF THE ESTATE OF JENELL S. PUTNAM, DECEASED, incorporates by reference all the preceding paragraphs as fully set forth herein paragraphs and further alleges as follows:

134. The Defendants labeled, promoted, and advertised the Liberty Cycler System as safe, fit and effective for use in humans.

135. The Defendants are the manufacturers, designers, distributors, sellers or suppliers of the Liberty Cycler System and, while engaged in the course of such business, made

representations to Plaintiff and Plaintiff's healthcare providers regarding the character and/or quality of the Liberty Cycler System for guidance in their decision to select the Liberty Cycler System for Plaintiff's use.

136. These representations included that the Liberty Cycler System was a safe and effective home peritoneal dialysis system.

137. Defendants knew that the Liberty Cycler System could leak and contaminate dialysate, thereby giving rise to peritonitis infection, subjecting Plaintiff to unnecessary pain and suffering, debilitation, complications, and possible death. The fact that the Liberty Cycler System could leak and contaminate dialysate is a material fact.

138. Had Plaintiff and/or her healthcare providers been aware of the hazards associated with the Liberty Cycler System Plaintiff would not have used the Liberty Cycler System.

139. Defendants' advertisements, which Defendants knew to be false, for the purpose of fraudulently inducing consumers and healthcare providers, such as Plaintiff and her healthcare providers, to use such products. Plaintiff and/or her healthcare providers relied on these material misrepresentations when deciding to prescribe and use the Liberty Cycler System.

140. Defendants acted willfully in deceiving Plaintiff and/or her healthcare providers regarding the safety and efficacy of the Liberty Cycler System in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use the Liberty Cycler System.

141. Defendants fraudulently concealed material information regarding the safety and efficacy of the Liberty Cycler System, including information regarding increased adverse events, including an unacceptable risk of leak, contamination and infection. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep sales of the Liberty Cycler System high.

142. Defendants fraudulently concealed safety issues with the Liberty Cycler System in order to induce healthcare providers, and patients, including Plaintiff and/or her healthcare providers, to use the Liberty Cycler System.

143. At the time Defendants concealed the fact that the Liberty Cycler System was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with the Liberty Cycler System.

144. Plaintiff and/or Plaintiff's healthcare providers reasonably relied, to their detriment, upon the Defendants' actions, concealment and omissions in their representations concerning the effectiveness, safe, and risks of the Liberty Cycler System.

145. In reliance on Defendants' misrepresentations of material fact, Plaintiff and/or Plaintiff's healthcare providers decided to use and did use the Liberty Cycler System for Plaintiff. Had Plaintiff and/or her healthcare providers known the true facts regarding the Liberty Cycler System, Plaintiff would not have consented to using the Liberty Cycler System. Had Plaintiff's healthcare providers known the true facts regarding the Liberty Cycler System, they would not have used the Liberty Cycler System for Plaintiff.

146. Upon information and belief, Plaintiff alleges that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with the Liberty Cycler System with the purpose of preventing consumers and healthcare providers, such as Plaintiff and/or her healthcare providers, from discovering these hazards.

147. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the Liberty Cycler System as described herein. Defendants did not disclose this information to the Plaintiff, her healthcare providers, the

healthcare community and the general public. The dangers associated with the Liberty Cycler System were not known to the general public or to Plaintiff until after Plaintiff contracted peritonitis from her Liberty Cycler System. Without full knowledge of the dangers of the Liberty Cycler System, Plaintiff could not, through reasonable diligence, discover that Plaintiff had a valid claim.

148. As a direct and proximate result of the defective manufacturing and the unreasonably dangerous and defective characteristics of the Liberty Cycler System and the Defendants' failure to comply with federal standards and requirements, the Plaintiff/Decedent suffered severe and permanent injuries. Plaintiff/Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff/Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff/Decedent suffered pecuniary loss. Plaintiff/Decedent seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein were permanent.

149. Defendants acted willfully or with gross negligence indicating a wanton disregard for the rights of Plaintiff/Decedent and others, rendering Defendants liable to Plaintiff/Decedent for punitive damages. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff/Decedent herein, thereby entitling Plaintiff/Decedent to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

150. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff/Decedent herein, thereby entitling Plaintiff/Decedent to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF
(DAMAGES)

WHEREFORE, Plaintiffs respectfully request the following relief:

a. Judgment against the defendant in an amount in excess of seventy-five thousand dollars ($75,000.00), this court's jurisdictional requirement, for compensatory damages;

b. Economic losses;

c. An award for medical expenses incurred by the decedent, JENELL S. PUTNAM, past, present and future;

d. An award for physical pain and suffering sustained by the decedent, JENELL S. PUTNAM, prior to her death;

e. An award for mental anguish and emotional distress sustained by the deceased, JENELL S. PUTNAM, prior to her death;

f. An award for loss of enjoyment of life sustained by the decedent, JENELL S. PUTNAM, prior to her death;

g. An award for costs, expert witness fees, reasonable attorneys' fees, pre-judgment and post-judgment interest, disbursements and other appropriate and necessary costs of maintaining this action as may be permitted by law.

h. An award for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees;

i. Any further relief as this Court deems just and proper.

REQUEST FOR JURY TRIAL

Plaintiff demands a trial by jury of six on all issues of this case.

Dated: June 27th, 2016.

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